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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,200	07/23/2003	Shlomo Raz	AMS-155	1238
43554	7590	12/04/2006	EXAMINER	
FAEGRE & BENSON PATENT DOCKETING 2200 WELLS FARGO CENTER 90 SOUTH SEVENTH STREET MINNEAPOLIS, MN 55402-3901			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/04/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/625,200	RAZ ET AL.
	Examiner William H. Matthews (Howie)	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 November 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17, 19, 21, 22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17, 19, 21, 22, 24-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's amendment to claim 19 now reads on the elected species, therefore claim 19 is no longer withdrawn.

### ***Response to Arguments***

1. Applicant's arguments filed 11-9-06 have been fully considered but they are not persuasive.
2. Regarding Tovey, Applicant contends Tovey lacks a substantially cylindrical body having a bore extending perpendicular to the longitudinal axis of the cylindrical body and a suture securing the anchor to the implant. Examiner disagrees because the Tovey anchor is considered to be substantially cylindrical and the bore is perpendicular to the longitudinal axis of the anchor because the cylindrical shape is shorter in width. The sutures connect the anchors to end portions of the implant via additional anchors as shown in Figures 8-9.
3. Regarding Gellman, Applicant contends Gellman lack substantially cylindrical anchors. Examiner disagrees because Gellman figure 11 show a cylindrical anchor having a bore perpendicular to the longitudinal axis. Furthermore, in column 16 lines 20-43 Gellman cites 08/385,897 (US PN 5766221) as an example of the anchor system. In the '221 patent, Figure 18 clearly show a cylindrical body having bore perpendicular to the longitudinal axis.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 27 recites "perineal incision" (final line) in combination with "vaginal incision" (preamble). The specification at page 11 only describes a perineal incision with male incontinence treatment.

7. Claims 24,25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 5 of claim 24, "the cylindrical body" lacks proper antecedence. Claim 25 depends from cancelled claim 1.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 17, 19, 21, 22, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Tovey US PN 5,333,624.

Tovey discloses in figures 1, 6, 7, and 9-12 a system for inserting a sling comprising a rectangular sling 9, sling anchors 10 having a cylindrical body 14 with a perpendicular bore 15 therethrough, suture 19, and inserter 20. Although the sling anchors are not described to anchor the sling to internal soft tissues, ligaments, or fascia, the structure and shape of the anchors meet the claimed structural limitations

and are capable of anchoring the sling to internal soft tissues, ligaments, or fascia.

Note the limitations of claim 17 regarding requiring an incision or not are intended use recitations that do not structurally limit the device.

3. Claims 17, 19, 21, 22, and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Gellman et al. US PN 6,042,534.

Gellman et al. discloses in figures 2c and 14 a system for inserting a sling comprising a rectangular sling 10, suture 64, sling anchors 62 having a cylindrical body with perpendicular bore therethrough, and inserter. See anchors in figure 11 as well as figure 18 of USPN 5766221 (incorporated by reference at lines 24-28 of col. 16). The inserter and anchors are described at lines 20-43 of col. 16. Although the sling anchors are not described to anchor the sling to internal soft tissues, ligaments, or fascia, the structure and shape of the anchors meet the claimed structural limitations and are capable of anchoring the sling to internal soft tissues, ligaments, or fascia. Note the limitations of claim 17 regarding requiring an incision or not are intended use recitations that do not structurally limit the device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Matthews (Howie)  
Examiner  
Art Unit 3738